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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,357	07/30/2003	Sammy S. Datwani	100/17201	9263

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EXAMINER	
WALLENHORST, MAUREEN	

ART UNIT	PAPER NUMBER
1743	

DATE MAILED: 11/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/630,357	DATWANI ET AL.	
	Examiner	Art Unit	
	Maureen M. Wallenhorst	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *75-102* is/are pending in the application.

4a) Of the above claim(s) *1-74* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *75-102* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/1/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. Applicant's election without traverse of Group III, claims 75-102 in the reply filed on October 25, 2006 is acknowledged.

2. Claim 97 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

On line 2 of claim 97, the word "transferring" is indefinite since claims 96 and 82, from which claim 97 depends, do not positively recite any step of transferring reagents or solvents.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 75-78 and 82-98 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolk et al (US Patent no. 6,620,625, submitted in the Information Disclosure Statement filed on March 1, 2004) in view of Ezrielev et al (US Patent no. 5,476,792).

Wolk et al teach of an ultra high throughput sampling and analysis system used for sampling large numbers of different materials from surfaces of substantially planar library storage components. The system comprises a substrate 704 that has a large number of discrete quantities of different test compounds of reagents removably immobilized thereon. Removably immobilized means that the sample materials are present upon the sample substrate in an immobilized format (confined in a discrete region), but are removable from the substrate through appropriate action. The samples are deposited on the substrate in an array and dried. The samples are removable by dissolving them in a fluid and pulling the fluid off the sample substrate. The sample fluids may be coupled to the substrate through ionic, hydrophobic or hydrophilic interactions, and covalent interactions, which are severable by exposing the substrate to an appropriate environment such as a certain buffer solution, thermal environment, etc. Hydrophobic barriers surrounding hydrophilic regions may be present on the substrate to separate the individual reagent spots, or vice-versa. The substrate can be made out of a non-porous material such as glass, silicon or a polymer. The substrate surface may have a coating thereon such as a glass substrate coated with a silane material or a surface containing a polymeric or metallic coating. The substrates can have a pattern thereon such as a honeycomb pattern with

uniformly spaced pores for holding the reagent spots. The reagent spots can comprises proteins, peptides, nucleic acids and the like. The compounds that are spotted onto the substrate comprise in addition to the particular compound at least one excipient material that enhances one or more of the deposition and/or solubilization of the compound in an appropriate solubilization liquid. Examples of excipients include polymers such as PEG, detergents, sugars and solvents such as DMSO. See lines 42-65 in column 13 and lines 12-17 in column 27 of Wolk et al. An automated system is used to position the substrate in relation to a microfluidic device having an external sampling capillary element 106 attached thereto. The substrate and microfluidic device can be positioned on a platform that is movable in the X-Y-Z direction so as to move the array and microfluidic device relative to one another. Wolk et al teach that the substrate may contain alignment marks thereon that are marks on the array that correspond to a certain position on the array. The alignment marks may contain material that makes them fluoresce and be opaque. An imaging system is used to locate the alignment marks on the substrate in order to position the capillary element 106 of the microfluidic device above one of the reagent spots on the array. Once a reagent spot is located by means of the alignment marks, the capillary element serves to dispense a solvent or buffer solution to the reagent spot in order to dissolve the reagent spot. The dissolved reagent is then aspirated by the capillary element 106 so as to enter into the microfluidic device for analysis. See figures 1, 6 and 7a, lines 9-62 in column 2, lines 36-67 of column 4, lines 8-30 in column 5, lines 32-65 in column 9, lines 34-64 in column 11, lines 24-43 in column 12, lines 42-65 in column 13, lines 19-44 in column 19, lines 15-67 in column 20, lines 1-11 in column 21 and lines 12-28 in column 27 of Wolk et al. Wolk et al fail to teach that the alignment marks on the substrate comprise a water insoluble polymer, a dye and a solvent.

Ezrielev et al teach of a time-temperature indicator device that contains a substrate having different spots of a dye-compatible polymer composition attached thereto. The dye-polymer composition spots serve to change color upon exposure to a certain temperature over a certain time period. The polymer in the compositions can be a polyester or polyethylene. The dye can be a solvent dye such as an azo, a diazo, an anthraquinone dye or a phthalocyanine dye. In addition, the compositions can contain additives therein such as various solvents. The polymer-dye compositions are applied to a substrate in a pattern. See figures 1-1b. Ezrielev et al teach that the substrate can also contain indexing lines or reference marks thereon formed of the same dye-polymer composition as the spots that form a visualizing area of the device, wherein progressive coloration of the polymer composition may be observed. See lines 19-67 in column 4, lines 18-49 in column 6, lines 31-42 in column 7 and lines 35-39 in column 12 of Ezrielev et al.

Based upon a combination of Wolk et al and Ezrielev et al, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to manufacture the alignment marks on the substrate taught by Wolk et al out of a composition containing a polymer, a dye and a solvent since Wolk et al teach that 1) the alignment marks must be visually detectable by an imaging system, thus making it advantageous to include a dye in the marks, 2) the marks may exhibit fluorescent properties and be opaque (see lines 60-67 in column 20 of Wolk et al), thus suggesting that the marks contain a dye therein, and 3) the compositions applied to the substrate advantageously contain a polymer and a solvent such as DMSO therein in order to enhance the adhesion of the compositions to the substrates, and Ezrielev et al teach that reference marks on a

substrate device used as an indicator may contain a dye, a polymer and a solvent therein in order to render the marks visible and adherent to the substrate.

7. Claims 79-81 and 99-102 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolk et al in view of Ezrielev et al as applied to claims 75-78 and 82-98 above, and further in view of Wagner et al (US Patent no. 6,475,809). For a teaching of Wolk et al and Ezrielev et al, see previous paragraphs in this Office action. Wolk et al fail to teach that the substrate on which the array of reagents is spotted comprises a self-assembled monolayer formed at an interface on the substrate surface.

Wagner et al teach of protein arrays for high-throughput screening. The device comprises a substrate having a plurality of spots of proteins arranged in discrete, known locations. The proteins are spaced from one another in rows and columns from about 50 nm to about 500 micrometers apart. The substrate can be made of glass, silicon, silica, a polymer or a metal. In a preferred embodiment, the proteins are attached onto a self-assembled monolayer that is attached to an interface on the substrate. The monolayer contains molecules of the formula X-R-Y, wherein R is a spacer, X is a functional group that binds R to the surface, and Y is a functional group for binding proteins onto the monolayer. The array may also comprise a coating between the substrate and the monolayer. The coating is applied to the substrate using techniques such as physical vapor deposition or chemical vapor deposition. The coating may comprise a metal film such as aluminum, chromium, gold or silver. The coatings may require an adhesion layer between the coating and the substrate such as a layer of titanium. The deposition of the coating on the substrate is done prior to the formation of patches of proteins thereon. Monolayer-compatible surface coatings may be fabricated in a pattern onto the substrate using

photolithography, chemical etching or micro molding. Protein patches are then formed in the openings of the pattern. Diffusion boundaries between the openings of the pattern are formed as walls of substrate material or photo resist. The walls of the pattern are used to separate the protein patches from one another. In a preferred embodiment, the patches or openings are separated from one another by surfaces of the substrate free of monolayer of the form X-R-Y. Alternatively, non-bioreactive monolayers with a different wettability may be used to separate patches of proteins from one another. See Figure 2 in Wagner et al that depicts a coating 5 on a substrate 3, an adhesion interlayer 6 and a monolayer 7. The R group in the self-assembled monolayer comprises a hydrocarbon chain of from about 1 to 200 carbons long. Preferably the R is an alkyl chain having about 8 to 22 carbons, such as a straight alkane. X is any group that affords chemisorption or physisorption of the monolayer onto the surface of the substrate (or the coating if present). When the substrate or coating is a metal, X is chosen to be a disulfide, a sulfide, a thiol or a trivalent phosphorus compound. This embodiment is preferred when the coating or substrate is gold or silver. If the substrate is a glass or silicon material, X is preferably a silane material such as a monohalosilane, a dihalosilane, etc. When the surface of the substrate is composed of a metal oxide, X is preferably a carboxylic acid. The component Y of the monolayer is a functional group responsible for binding a protein onto the monolayer. The Y group may form a covalent or noncovalent linkage with the protein. Possible Y groups include -OH, NH2, -COOH, -PO4, SO3, etc. Wagner et al teach that a method of using the protein array attached to a self-assembled monolayer on a substrate involves screening the proteins for their ability to interact with a component of a fluid sample. The method of use comprises delivering a fluid sample to the array, and detecting the interaction of the component with the immobilized

protein of each patch or spot. See figures 1, 3, 4-7, lines 57-67 in column 7, lines 1-67 in column 8, lines 1-67 in column 9, lines 1-63 in column 10, lines 25-35 in column 11, lines 3-39 in column 12, and lines 40-46 in column 17 of Wagner et al.

Based upon the combination of Wolk et al, Ezrielev et al and Wagner et al, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to attach the array of reagents taught by Wolk et al onto a self-assembled monolayer formed at an interface of the substrate since Wolk et al teach that the reagents must be reversibly attached to the substrate in an ordered array, and Wagner et al teach that self-assembled monolayers attached to an interface of a substrate allows reagent materials such as proteins to be reversibly attached to the substrate in an organized and ordered array without the broad and irregular spreading of the protein spots into one another. Thus, the provision of a self-assembled monolayer at an interface on the substrate taught by Wolk et al would allow for a more consistent and uniform surface to receive the reagents of the array without any cross contamination.

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Please make note of: Charych (WO 01/01142) who teaches of arrays of biopolymeric agents on a substrate, wherein the substrate has a self-assembled monolayer thereon.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Thursday from 6:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maureen M. Wallenhorst
Primary Examiner
Art Unit 1743

mmw

November 9, 2006

Maureen M. Wallenhorst
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